PROTOCOL FOR ISSUING PUBLIC HEALTH ADVISORIES FOR CHEMICAL CONTAMINANTS IN RECREATIONALLY CAUGHT FISH AND SHELLFISH

DRAFT FOR PUBLIC COMMENT

Prepared by

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PREAMBLE

The protocol for Louisiana's fish and shellfish advisories is designed to provide standardized guidelines regarding the development and issuance of fish and shellfish consumption advisories while allowing for the incorporation of site-specific data that are reliable and validated. The steps in the process, such as investigation of contaminants in fish tissue, determination of the need for an advisory, and the ultimate interagency consultation, follow the same procedural steps for each location, but variations in advisory procedures or recommendations may occur due to the consideration of appropriate site specific factors. These factors include issues such as site-specific data quality, species and size of contaminated fish, distribution of the contaminant within the organism, presence of single or multiple contaminants, toxicological properties of the contaminant, and characteristics of the affected population. The Louisiana Department of Health and Hospitals (LDHH) in coordination with the Louisiana Department of Environmental Quality (LDEQ), Louisiana Department of Wildlife and Fisheries (LDWF) and Louisiana Department of Agriculture and Forestry (LDAF), seeks to inform the public, in an expedient manner, of the potential risks of fish and shellfish consumption while advocating full enjoyment of Louisiana's delicious and abundant fish and shellfish resources.

All requests for copies of this document should be directed to the Louisiana Department of Health and Hospitals, Office of Public Health, Section of Environmental Epidemiology and Toxicology (SEET). The SEET may be contacted as follows:

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This document is also available on the Internet on the LDHH SEET website: http://www.dhh.louisiana.gov/offices/page.asp?id=205&detail=5749 and the LDEQ Water Quality Division (WQD) website: http://www.deq.louisiana.gov/portal/Default.aspx?tabid=1631

1.0 INTRODUCTION

Chemicals released to the environment from point sources such as industrial and municipal discharges and from nonpoint sources such as agricultural runoff and atmospheric deposition have contaminated some surface waterbodies in the State of Louisiana. Many chemical contaminants concentrate in fish and shellfish by accumulating in fatty tissues or selectively binding to muscle tissue (the fillet). Even extremely low concentrations of bioaccumulative chemicals in a waterbody may result in fish or shellfish tissue concentrations high enough to pose health risks to fish consumers.

In order to safeguard and protect public health from chemically-contaminated fish / shellfish, consumption advisories may be issued in Louisiana from time to time, and have been issued since the early 1980s. This protocol provides a standardized approach for the development and issuance of fish / shellfish consumption advisories in the State of Louisiana. The purpose of a consumption advisory is to reduce or eliminate possible adverse public health impacts due to the ingestion of toxic substances present in some fish and shellfish. Advisory recommendations primarily pertain to the consumption of recreationally-caught fish and shellfish. During the advisory process, information such as the species and sizes of fish / shellfish affected, the contaminants present, their concentrations and distribution within organisms, the physical, chemical and toxicological properties of the contaminants, and local population consumption practices and customs are evaluated using standard risk assessment methods. The results of this evaluation are used to determine if an advisory is needed, and if so, define the amount of fish / shellfish that can be safely consumed from the waterbody.

Risk assessment and risk management of chemically-contaminated fish are complex processes because of the many considerations involved in setting fish consumption advisories, including both the health risks and benefits of fish consumption and the potential impact of advisories on economic and societal factors. Therefore, even though the steps in the advisory process, such as the investigation of contaminants in fish tissue, the assessment of health risks, and the ultimate interagency consultation are the same for each waterbody evaluated, the basis of decision for different advisories may vary due to the consideration of various site-specific factors.

A listing of consumption advisories currently in effect in the State of Louisiana may be obtained at LDHH's website: http://www.dhh.louisiana.gov/offices/page.asp?id=205&detail=5749; or LDEQ's website: http://www.deq.louisiana.gov/portal/tabid/1631/ Default.aspx.

1.1 Basis of Authority

The Louisiana Departments of Health and Hospitals (LDHH), Environmental Quality (LDEQ), Wildlife and Fisheries (LDWF), and Agriculture and Forestry (LDAF) are authorized to protect public health and the environment. The LDHH, LDEQ and LDAF may recommend to the LDWF and the Wildlife and Fisheries Commission (LWFC) that fishing in an area be closed or regulated due to chemical contamination. The LDHH issues advisories in accordance with

Louisiana Revised Statutes (L.R.S.) 40: 4A(13), 40:5(20), and 36:258B. The LDEQ issues advisories in accordance with LRS 30:2074.B.1. The LWFC functions by authorities presented in L.R.S. 56:5, 6 and 22. The LDWF operates as the enforcement and analytical body of the aforementioned Commission. The LDAF has statutory authority to issue appropriate orders to mitigate and / or remediate pesticide contamination as per L.R.S. 3:3277, 3:3308 and Louisiana Administrative Code 7:XXIII.213.



2.0 CATEGORIES OF PUBLIC HEALTH ADVISORIES

2.1 Interim Health Advisory

An interim health advisory is issued when the State Health Officer decides that compelling but insufficient data exist to suggest a potential health threat to the public. Additional data will be collected and analyzed within one year of imposing an interim advisory to confirm or disprove that a health threat exists. Therefore, the interim advisory is only a temporary alert to the public and is expanded or lifted depending on the results of additional sampling and analyses. Within one year the interim advisory will be converted to a fish / shellfish consumption advisory or rescinded.

2.2 Fish and Shellfish Consumption Advisory

A fish and shellfish consumption advisory is issued when sufficient chemical contamination data exists to support a recommendation to limit the amount of fish and shellfish eaten from a particular water body. When health guidelines are exceeded, restrictions on the amount and type of fish and shellfish eaten are needed to protect human health. To meet this goal, fish and shellfish consumption advisories may recommend limits on consumption of a specific type of fish and shellfish or may recommend limits on consumption by a particular population, such as pregnant and breast-feeding women. Usually, the fish and shellfish consumption advisory recommends a certain number of meals per week or month. Recommendations regarding food preparation and health effects associated with the chemicals of concern are also provided in each advisory message.

3.0 FISH AND SHELLFISH CONSUMPTION ADVISORY PROCESS

Fish / shellfish consumption advisories warn the public which fish and shellfish contaminant levels pose a health risk to the public. The advisory process utilizes biota sampling results in conjunction with risk assessment to characterize the need for a consumption advisory at a particular waterbody. The steps involved in the advisory process are described in the following sections.

3.1 Determine the Need for an Advisory

Suspicion of significant fish tissue contamination may result from existing data on environmental media (e.g., sediment, soil, water, biota), from the occurrence of localized chemical releases to surface water (some of which may have occurred in the distant past), from knowledge of widespread environmental contamination issues, or from other means. Preliminary data collection is designed to screen targeted waterbodies in an efficient manner. For cost-effectiveness, the Environmental Protection Agency (EPA) recommends that states collect only one size class for each target species and focus on the larger fish within a species commonly harvested by the local population (EPA, 2000). In this way, the states will maximize their chances of detecting high levels of chemical contamination in the single composite sample collected for each target species. When fish-tissue contamination is detected in preliminary screenings, the waterbody is targeted for further evaluation (see Section 3.1.1). While EPA does not recommend a standard default sample size, general guidelines for determining sample sizes are presented in Guidance for Assessing Chemical Contaminant Data for Use in Fish Advisories Volume I Fish Sampling and Analysis (EPA, 2000). At any point in this process an advisory can be issued in the interest of protecting public health when compelling data exist, such as inordinately high contaminant levels, even when these data are insufficient.

3.1.1 Step 1 – Data Collection

When preliminary data suggest potential fish-tissue contamination, a more extensive, comprehensive data evaluation or collection is conducted. The objective of conducting a comprehensive data collection effort is to provide adequate characterization of the contaminant concentrations in the edible species to support the risk assessment and advisory process. The list of target analytes is based on known contaminants in sediments or waters, known discharges from nearby industries, and contaminants such as chlorinated pesticides known to be highly bioaccumulative, and therefore, likely to be concentrated in aquatic organisms.

The laboratory analysis of fish and shellfish tissue for chemical contaminants is performed according to applicable state and federal quality assurance procedures. The agencies ensure the accuracy, precision, and reliability of the data generated, as well as the use of the department-approved methodologies in the generation of that data. If the contaminant is a pesticide or is agricultural in origin, laboratories operated by LDAF may be utilized. To expedite the advisory process, analyses may be performed by the LDHH Laboratory Services Division. Quality control and

assurance associated with the samples' handling, preparation and analyses are reviewed and must meet the requirements of LDEQ, LDHH, LDWF and LDAF.

3.1.1.1 Target Species

During the screening process, fish species selected for analyses should include those most representative of the following niches or trophic levels depending on the contaminant of concern: bottom-feeders, predators and browsers / foragers. In freshwater ecosystems, at least one bottomfeeding and one predator fish species should be collected. In estuarine or marine ecosystems, either one bivalve and one finfish species or two finfish species should be collected. More comprehensive sampling will be conducted after preliminary sampling indicates consistently excessive fish-tissue contamination, and will include a wide range of age / size classes from each target species to provide information on the nature and extent of contamination within the given fish population. When data from these samples indicate contaminant levels that may be of a human health concern but data are not adequate for determining advisory needs, additional sampling may be conducted to provide more information specific to those fish species and age / size classes to which anglers of those waters would most likely be exposed. Target species should include all species commonly caught and consumed by area anglers. While the EPA's advisory guidance document (EPA, 2000) only makes recommendations for the sampling of bottom-feeders and predators, many browsers / foragers are captured and consumed in Louisiana (e.g., bluegills). Thus, browsers / foragers may also be collected to fully represent Louisiana's aquatic food web. Creel surveys, if available, are valuable to determine what fish and / or shellfish are caught and the consumption patterns of anglers in the area.

3.1.1.2 Individual vs. Composite Samples

Fish tissue samples submitted for analyses may represent individual specimens or a composite of individuals. Composite sample analyses provide an estimate of the average contaminant concentration across a group of individual fish within a species and can be a cost effective way to provide data on more fish. However, if size of the fish and/or cost of analyses allow, analyses of individual fish samples may be performed which provide more detailed information of the presence of a given contaminant within that species population.

Composite samples are generated by removing targeted tissue from several fish of the same species and same size (\pm 15% by length) and placing the tissue in a single sample container as per approved protocols. A good quality control practice is to periodically provide for a duplicate sample of a submitted composite (5-20% of all samples). The duplicate may be generated by using the target tissue from the opposite side of the fish (i.e., right-side fillet for composite sample and left-side for duplicate composite sample). Duplicates may also be produced by laying the rendered fillets from each individual in an alternating orientation of head to tail, then tail to head, etc. and cutting the stack of fillets to split the tissue sample. This method can be used when sufficient tissue is available so as not to require tissue removal from the opposite side of the individual fish.

Individual samples are generated by removing target tissue from one specimen and placing the tissue in a single sample container as per approved protocols. Individual samples are used when fish size and/or monetary resources for analytical services are not limiting; when more detailed information of the variability of a given contaminant among individuals is desired; and / or when only one individual of a particular size class is available for analyses, such as with a particularly large or uncommon specimen. A duplicate for individual samples should be generated periodically by using the target tissue from the opposite side of the fish (i.e., right-side fillet for sample and left-side for duplicate sample).

The amount of tissue provided for a given sample should be approximately 200 grams (wet weight), but this will vary with the laboratory and analyses. Samplers should discuss sample mass with the receiving laboratory prior to initiating sampling.

3.1.1.3 Tissue Cuts

The advisory development process in Louisiana is based on analyses of edible tissues. Typically, this means muscle tissue fillets without skin, bones, or organs. For species where organs are also considered edible, the organs may be included with the muscle tissue for analysis, and / or analyzed separately, when differences exist in population consumption habits. For example, edible tissue of crabs typically includes all leg and claw meat, back shell meat, and body cavity meat. The hepatopancreas ("crab fat") may be included for analysis as determined by the eating habits of the local population or subpopulations of concern. However, fat should be analyzed separately to enable the evaluation of health risks associated with consuming crabs of variable fat content. When assumptions are made regarding the removal of fat prior to consumption, guidance statements attesting to such are included in the advisory. Hard- and soft-shelled crabs should not be combined in the same composite.

3.1.1.4 Sample Preparation and Quality Assurance / Quality Control (QA/QC) Measures

Samples should be collected, preserved, processed, and analyzed according to scientifically valid, cost-effective, standardized procedures as discussed in the most current version of *Guidance for Assessing Chemical Contamination Data for Use in Fish Advisories Volume 1 Fish Sampling and Analysis* (EPA 2000). The integrity and security of samples and data should be maintained at all times. Record keeping and documentation procedures should be adequate to ensure traceability of all samples and data from initial sample collection through final reporting and archiving, and to ensure the verifiability and defensibility of reported results. Data quality should be assessed, documented, and reported properly. Reported results should be complete, accurate, and comparable with those from other similar monitoring programs. Quality control and assurance practices used should be at least equivalent to those described by the LDEQ Quality Management Plan to ensure that the quality of data created or received by LDEQ complies with its data policy.

Laboratory results should be reported with any information necessary to ensure the validity of the sample. Supporting documentation should include, when available, analyte name, waterbody name, sampling location (monitoring station identification or latitude / longitude coordinates), sampling date, sample collection procedures, sample preservation and processing procedures, analytical methods used for quantitation of target contaminants, method detection and quantitation limits, percent lipid composition, species name, composite sample identification (ID) number, sample size for each composite sample, fish length (average individual lengths for each fish in a composite), estimated age, sample weight, tissue cut type analyzed, indication of the presence or absence of contaminant detection (yes / no), QA / QC results (i.e., blank results, spiked samples results, split sample results, equipment calibration results, internal QA /QC check results, etc.), a detailed description of recordkeeping and documentation procedures for maintaining laboratory log books and reporting forms, significant figures, units of reporting, routine procedures to assess the accuracy and completeness of records, and a detailed description of the database variables and layout for transparent oversight.

Any events that occur during sample handling that may affect the integrity of the data will be noted on the field data sheet and on the laboratory data forms. Deviations and events will be reviewed to determine if the impact causes a sample or resulting data to be invalid. All sampling will be conducted according to the quality assurance and control procedures referenced in the most current version of *Guidance for Assessing Chemical Contamination Data for Use in Fish Advisories Volume 1 Fish Sampling and Analysis* (EPA 2000).

Duplicate fish tissue data will be qualified using relative percent difference (RPD). If the RPD is greater than 100%, the sample will be rejected. The RPD (%) is calculated as the absolute value of:

$$\left[\frac{(x_1 - x_2)}{\frac{x_1 + x_2}{2}}\right] *100$$

where:

 x_1 = Concentration observed in the original sample;

 x_2 = Concentration observed in the duplicate sample.

3.1.1.5 Analytical Parameters and Required Detection Limits

The analyte list for preliminary data collection efforts should include all bioaccumulative chemicals known or suspected to be present in the waterbody. In general, chemicals that have the potential to bioaccumulate are identified as having a log K_{ow} greater than or equal to 2.3 (EPA, 1989). Commonly encountered bioaccumulative analytes include, but are not limited to, organochlorine pesticides, polychlorinated biphenyls, polychlorinated dibenzodioxins and

dibenzofurans, certain other organochlorine compounds (such as chlorinated benzenes, styrenes and butadienes) and certain metals. The final analyte list used for comprehensive sampling efforts should include all chemicals detected at levels of potential concern during the preliminary sampling event.

The analytical capabilities and quality control procedures of the laboratory tests used in measuring concentrations in solid media (tissue) also need to be considered. In order to obtain data that are suitable for risk assessment and the advisory process, it is imperative that the reporting limits (RL) in tissue are within the analytical capabilities of the analytical method and laboratory techniques employed and below levels that represent health concerns. EPA guidance recommends that the reporting limit (RL) for tissue analysis be at least five times lower than the screening value for a given target analyte (EPA, 2000, Vol.1). In general, laboratories conducting the analytical evaluation of fish tissues should have instrument detection limits in the sub-parts per trillion (ppt) range. A list of EPA-recommended detection limits for commonly encountered bioaccumulative contaminants is provided in the most current version of EPA's *Guidance for Assessing Chemical Contamination Data for Use in Fish Advisories Volume I Fish Sampling and Analysis*.

3.1.2 Step 2 - Review and Evaluate Data

Following laboratory testing, data are supplied to LDHH for review. Data evaluated include those received from state agencies (LDEQ, LDWF, LDAF), federal agencies (EPA, ATSDR), principal responsible parties (PRPs), non-governmental organizations (NGOs), or other sources. Evaluations are generally limited to data from the last three years of available data to ensure that recommendations are relevant to the current conditions. Data collected during infrequent events (such as hurricanes and remediation events) are included in the analyses as these events are representative of potential exposures during real-world events. Data accepted for evaluation are verified and must meet QA/QC criteria set forth in Section 3.1.1.4 and data quality objectives presented in Section 3.1.2.1.

3.1.2.1 Data Quality Objectives

Many elements of the risk assessment process involve significant uncertainty (e.g. due to spatial and temporal variability in species- and tissue-specific contaminant levels; the effects of concurrent exposures to a mixture of contaminants from other sources or species; variations in areaspecific and species-specific consumption rates or population profiles; etc.). Data gaps can add significantly to the uncertainty associated with exposure and risk assessment (e.g., where deficiencies are noted with respect to insufficient sampling of all species of concern; number of fish collected per sample; size or weight of fish collected; area fish collected from; etc.).

Under these circumstances, data will be reviewed for comprehensiveness and data limitations will be identified. Where possible, recommendations for re-sampling and / or -analysis will be made to minimize uncertainty. However, in the event significant uncertainties remain, health-conservative

assumptions will be used to ensure the protection of public health. It should be noted that, divergence from default assumptions may occur.

The primary data quality objectives include but are not limited to the following: (1) samples are collected, processed and analyzed according to scientifically valid, standardized procedures; (2) record keeping and documentation procedures are adequate to ensure the traceability of all samples and data from initial sample collection through final reporting and archiving and to ensure the verifiability and defensibility of reported results; (3) field blanks (number and analyses) and field duplicates (number and analyses) are reported and indicate reproducibility; (4) data quality is assessed, documented, and reported properly, and reported results are complete and accurate; (5) sample specifics are noted and justifiable (target species and size class, sampling site locations, target contaminants, number of samples and fish per sample, tissue type analyzed); and (6) spatial and temporal variability are adequately characterized with an appropriate sample number.

3.1.2.2 Screening

Data meeting data quality objectives are segregated by species, location, and when there is sufficient data, by size. An arithmetic mean of contaminant concentration in wet weight is obtained for each species. The arithmetic mean contaminant concentration is used to represent the exposure concentration for edible fish / shellfish and is used in the screening and advisory process. Non-detect samples are included in the mean. Concentrations of contaminants which are below the reporting limit (RL) are assigned a value of zero if more than half of the samples were below the RL, otherwise they are assigned a value of one-half the RL. Those contaminants which are not detected or detected at very low average concentrations and do not pose a health threat are eliminated from further consideration.

Prior to initiating the public health advisory process, the species-specific mean contaminant concentration in fish / shellfish tissue is compared against the tissue screening level (TSL) to identify waterbodies, fish / shellfish species, and contaminants that require further evaluation. TSLs are screening values which are defined as concentrations of contaminants in fish or shellfish tissue that are of potential public health concern and that are used as thresholds against which levels of contamination in similar tissue collected from the ambient environment can be compared. TSL guidelines are available for selected contaminants on the LDEQ Water Quality Division (WQD) websites at the following URL: http://www.deq.louisiana.gov/portal/Default.aspx?tabid=1631. The TSLs will be revised as needed to ensure that the advisory process is based on the most current toxicity information available. If the mean concentration of a contaminant in fish / shellfish tissue exceeds the TSL, then the waterbody, contaminant(s), and / or fish / shellfish species of potential concern are further evaluated. The screening process provides a rapid measure for identifying waterbodies, chemicals, and fish / shellfish species of potential concern.

The EPA-recommended risk-based methods for developing screening values are presented in the U.S. EPA's "Guidance for Assessing Chemical Contaminant Data for Use in Fish Advisories"

(EPA, 2000). Methods presented in this guidance document are used in conjunction with the assumptions presented in Table 1 to develop Louisiana fish-tissue screening levels.

3.1.3 Step 3 - Perform Exposure and Toxicity Assessments

If the mean concentration of a contaminant in fish / shellfish tissue exceeds the TSL, then a comprehensive fish sampling plan is developed and implemented as discussed in Section 3.1.1. The resulting data are then used in the advisory process to calculate an allowable monthly meal limit as discussed below.

In order to determine if fish and shellfish consumption practices present an unacceptable risk to those who consume recreationally-caught fish and shellfish, exposure potential must be considered. The assessment of exposure requires assumptions be made, some of which are the fish / shellfish consumption rate (gm / day), frequency of exposure (meals / week), duration of exposure (years), and consumer body weight. Assumptions used in estimating exposure may vary depending on population characteristics. Sensitive sub-populations such as pregnant women and breast-feeding children are considered during the assessment. LDHH makes every attempt to use exposure assumptions that best characterize the local consumption habits and behaviors when assessing risk to a particular community. When there is doubt as to which assumptions most accurately reflect the exposure situation, LDHH's policy is to consider a worst-case scenario that gives the public more conservative, safer fish consumption recommendations.

The default exposure assumptions used in the advisory process are discussed below and summarized in Table 1.

Fish / Shellfish Consumption Rate. Anglers may be interviewed or creel surveys and / or needs assessments performed to determine the species and sizes which are commonly consumed. Fish / shellfish consumption rates vary in Louisiana, but resident consumption is usually estimated to range between 20 and 150 grams of fish per day. In the absence of sitespecific consumption data, advisories will be based on the default adult consumption rate and frequency of 30 grams per day for 365 days per year. This consumption rate equates to four eight-ounce meals / month and defines the exposure level that is used in calculating the monthly meal limit and in determining the need for a consumption advisory. A default consumption rate and frequency of 15 grams per day for 365 days per year (four four-ounce meals/month) will be assumed for children. When data are available and appropriate for the advisory process, the default consumption rate will be adjusted to account for site-specific exposure conditions. Local practices, customs, gender, age or health status should be considered in selection of the appropriate consumption rate. Other site-specific consumption data may be obtained from: 1) appropriate EPA guidance documents; 2) consumption surveys (what fish and how much is eaten); and 3) creel surveys (what fish species and size are actually caught and kept).

<u>Consumer Body Weight</u>. Advisories are issued for a standard population where the average adult individual is assumed to have a body weight of 70 kg (about 154 pounds) and an average child individual is assumed to have a body weight of 35 kg (EPA, 2000). This assumption is consistent EPA recommendations (EPA 1997; EPA 2000) and is used by EPA to derive toxicity values (EPA 2008). When specific sub-populations are targeted (children, women, difference ethnic groups, etc.), it is recommended that the population body weight assumptions be adjusted accordingly using either site-specific data, EPA default values (EPA 1997), or current U.S. Census Bureau population statistics.

Exposure Duration and Averaging Time. The exposure duration estimates the total time of exposure. EPA's fish guidance document does not define a single exposure duration assumption for all sites (EPA, 2000). In the absence of federal guidelines, the exposure duration, or duration of the consumption of fish / shellfish from the same waterbody, can be based on site-specific population mobility data for the area of concern. In the absence of site-specific mobility or exposure duration data, a reasonable maximum exposure default of 30 years is assumed. An exposure duration of 30 years represents the 90th percentile for the length of time a person resides at the same residence and hence is assumed to fish from the same waterbody (EPA 1991). This means that advisories are written with regards to protecting an individual who eats recreationally-captured seafood from a specific waterbody over an extended period of time. As such it is conservatively assumed that individuals will be exposed to the same contaminant level by eating fish from the same waterbody for the assumed exposure period.

The averaging time is the period over which exposure is averaged. The averaging time selected depends on the type of toxic effect being assessed. For long-term exposure, the averaging time is equal to the exposure duration. For carcinogens, total cumulative exposure is prorated over a lifetime. Therefore, the averaging time for carcinogens is 70 years (EPA, 2000).

The exposure level is integrated with a chemical-specific toxicity value to estimate the potential health risk. A toxicity value is a numerical expression of a chemical's dose-response relationship that is used to assess the health risk associated with chemical exposure. The sources of toxicity values include: EPA's Integrated Risk Information System (IRIS); Agency for Toxic Substances and Disease Registry (ATSDR); EPA's Provisional Peer Reviewed Toxicity Values (PPRTVs); other EPA sources, such as EPA's Health Effects Assessment Summary Table (HEAST) tier 3; and non-EPA sources such as the California EPA. The toxicity values most frequently used in the fish advisory process are EPA's reference dose and cancer slope factor. These values are described below. EPA recommends that when toxicity values are available for both carcinogenic and noncarcinogenic health effects for a compound, the health effect resulting in the most conservative meal consumption limit be used as the basis for the advisory.

<u>Reference Dose.</u> A reference dose (RfD) is an estimate of daily exposure (including sensitive populations) that are likely to be without appreciable risk of deleterious effects during a lifetime (EPA, 2000). Reference doses are expressed in terms of milligram of contaminant per kilogram of consumer body weight per day (mg/kg-d). The RfD is based on the premise that there is a threshold dose below which there are no noncarcinogenic health effects. The RfD is used to determine an acceptable daily intake for contaminants that may produce noncarcinogenic health effects. By integrating the RfD, the mean value of chemical concentrations in fish tissue, and standard default exposure assumptions (consumption rate, body weight, exposure duration), the acceptable consumption rate for fish/shellfish (i.e., acceptable monthly meal limit) can be determined. This information is then used to determine the necessity of a seafood consumption advisory.

Cancer Slope Factor. A cancer slope factor (CSF) is a plausible upper-bound estimate of the probability of a carcinogenic response per unit intake of a chemical over a lifetime of exposure to a particular level of a potential carcinogen. A CSF is expressed in units of risk per milligram of contaminant per kilogram of consumer body weight per day (risk/mg/kg-d). The CSF is based on the hypothesis that the mechanism for carcinogenesis is non-threshold because there is believed to be essentially no level of exposure to such a chemical that does not pose a finite probability, however small, of generating a carcinogenic response. The CSF is used to determine an acceptable daily intake for contaminants that may produce carcinogenic health effects. By integrating the CSF, a target risk level, the mean value of chemical concentrations in fish tissue, and standard default exposure assumptions (consumption rate, body weight, exposure duration), the acceptable consumption rate (acceptable monthly meal limit) for fish/shellfish can be determined. This information is then used to determine the necessity of a seafood consumption advisory.

3.1.3.1 Determine Site-Specific Meal Limits

This section presents the procedure, equations, and assumptions used in developing fish meal consumption limits for seafood advisory recommendations. The guidance provided in this section was adopted from EPA's "Guidance for Assessing Chemical Contaminant Data for Use in Fish Advisories" (Volume 2, EPA, 2000), and is discussed in greater detail elsewhere (SEET, 2007).

It should be stressed that the monthly consumption limits calculated as part of the advisory process pertain only to people regularly consuming fish caught in Louisiana waters. Consumption limits are designed to protect people who catch and consume fish from a specific waterbody for an extended period of time at a constant consumption rate.

If a calculated monthly meal limit is a fractional value, the value is rounded down to the nearest whole number so as not to exceed the maximum acceptable cancer risk or non-carcinogenic hazard index and ensure that public health is adequately protected.

When a contaminant has toxicity values for both carcinogenic and non-carcinogenic health effects, meal limits are calculated for both types of health effects. The health effect resulting in the more conservative monthly meal limit is used as the basis for the advisory. However, if only a carcinogenic toxicity value is available, then only a monthly meal limit for carcinogenic health effects is calculated. If only a noncarcinogenic toxicity value is available, then only a monthly meal limit for noncarcinogenic health effects is calculated.

Contaminant concentrations are generally derived from raw fillets that have had the skin and fat removed, unless site-specific data indicate otherwise (e.g., if a population eats other tissues, such as fat from crab, or organs from whole fish, then those tissues may be considered in the calculation of monthly meal limits). Advisories based on skin-, and fat-free fillets should include a statement recommending removal of skin and fat since these portions of the fish were not considered in the estimation of safe consumption limits.

The exposure assumptions considered in setting consumption advisories are summarized in Tables 1. It is important to note that site-specific data, passing data quality criteria, are preferred over default assumptions where available. When additional guidance is needed to address site-specific conditions, the guidelines provided in the U.S. EPA's "Guidance for Assessing Chemical Contaminant Data for Use in Fish Advisories" (Volumes 1-4; EPA, 2000) will prevail.

Methods for deriving consumption limits for both carcinogenic and non-carcinogenic compounds are presented below.

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Equation 1 is used to assess carcinogens and is derived from the basic formulas:
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Cancer Risk = Exposure (mg/kg-day) * Cancer Slope Factor (risk / (mg/kg-day)<sup>-1</sup>)
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where Exposure = Contaminant Concentration * Consumption Rate * Exposure Duration / Body weight * Averaging time
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Equation 4 is used to assess <u>non-carcinogenic toxicants</u> with non-cancer health effects and is derived from the basic formula:

```
Hazard Quotient = Exposure (mg/kg-day) / Reference Dose (mg/kg-day)
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The following equations are used to calculate a site-specific monthly meal limit for each target species.

Carcinogenic health effects for a single contaminant are calculated as presented below.

Equation 1 calculates an allowable daily consumption of contaminated fish and shellfish based on a compound's carcinogenicity.

CSF = Cancer Slope Factor ((mg / kg-day)⁻¹) = see IRIS C = Species avg. chemical Concentration (mg / kg or ppm) = mean

ED = Exposure Duration = 30 years

Equation 2 converts the maximum allowable consumption rate derived from **Eqn. 1** to the number of allowable meals per month:

Carcinogenic health effects for multiple contaminants are calculated as:

$$CR_c = \frac{R * BW * AT}{ED * [(CSF_1 * C_1) + (CSF_2 * C_2) + ... (CSF_i * C_i)]}$$
 EQN. 3

Equation 2 converts the maximum allowable consumption rate derived from **Eqn. 3** to the number of allowable meals per month.

Non-Carcinogenic health effects for a single contaminant are calculated as presented below.

Equation 4 calculates an allowable daily consumption of contaminated fish and shellfish based on a compound's non-carcinogenic health effect.

= Species avg. chem. Concentration (mg/kg or ppm)= mean

=70 kg

Equation 2 converts the maximum allowable fish and shellfish consumption rate derived from **Eqn. 4** to the number of allowable meals per month.

= Consumer Body Weight (kg)

Noncarcinogenic health effects for multiple contaminants with the same critical effect / target organ are calculated as:

$$CR_{nc} = THQ * BW* \left[\frac{RfD_1}{C_1} + \frac{RfD_2}{C_2} \dots \frac{RfD_i}{C_i} \right]$$
 EQN. 5

Equation 2 converts the maximum allowable fish and shellfish consumption rate derived from Eqn. 5 to the number of allowable meals per month.

If the contaminant elicits both carcinogenic and non-carcinogenic health effects, the maximum allowable fish consumption rates (CR) calculated for each type of health effect are compared and the lower of the two values is selected for calculation of the monthly meal limit (Equation 2).

For the purpose of determining the need for an advisory, an acceptable monthly meal limit is defined as four meals per month (52 weeks/year, 30 years). Therefore, a calculated monthly meal limit less than four meals per month indicates the need for a seafood consumption advisory. If a calculated monthly meal limit is a fractional value, the value is rounded down to the nearest whole number so as not to exceed the maximum acceptable cancer risk or non-carcinogenic hazard index and ensure that public health is adequately protected. A calculated allowable monthly meal limit may be modified if reliable and validated site-specific information is available.

3.2 Advisory Development

BW

C

If there are public health concerns associated with exposure to constituents, further evaluation may be incorporated into the decision-making process. Many factors go into the decision of whether to issue an advisory. Besides the quantitative estimates of population risk, other considerations include data quality / variability and societal impacts (e.g., impacts on community health, recreation, economics and traditions). While all risks and impacts are considered in some way, the agencies may elect to focus on one or a few of the potential risks or impacts. The EPA fish advisory guidance document gives suggestions for what to consider when determining the need to issue an advisory:

"It is suggested that the planning and evaluations for fish advisories be carried out on a site-specific basis whenever feasible. As discussed previously, local population characteristics and impacts on local traditions and economies may vary considerably from one area to another. Various types of information are required for decision-making. Some may be of a quantitative nature (e.g., risks associated with current consumption patterns, the estimated costs of various program activities, staffing requirements, impacts on property values). The quantitative values may be best estimates; however, this type of predictive information often contains significant uncertainty and should be considered accordingly. Most information collected for a fish advisory program will likely be of a qualitative nature (e.g., potential cultural impacts on targeted populations, nutritional impacts). Some form of risk characterization is also assumed to have been generated, although it may not be precise and should be considered a rough estimate even when detailed analyses have been carried out....Federal risk assessment methods were designed primarily to provide a means to establish exposure limits (e.g., for drinking water standards) and generate protective rather than predictive estimates. Consequently, the risk estimates should be considered an indication of maximum risk rather than a precise predictor of actual risk. As discussed previously, risk reduction through implementation of fish advisory programs are characterized as "benefits" for purposes of discussing advantages and disadvantages of various options. Benefits are those cases or people who would have been affected that were not affected as a result of reductions in their consumption of contaminated fish. A wide variety of risk management options have been considered in this document. The selection of which options to consider for inclusion in a fish advisory program is a critical decision. ...Restricting access to waterbodies or banning fishing may not be an option in areas where no regulatory authority is held by the overseeing fish contamination problems. (In most areas, however, the health department will have authority to restrict access in cases where a clear and present danger to the public exists.) Significant constraints on program options may also be imposed by budgetary or other conditions. ... The full spectrum of risk management options should be considered prior to selecting a particular subset of activities. This approach enables risk managers to review the advantages and disadvantages of all possibilities with

other interested parties, so that the final decisions may be considered objective and fully thought through." (EPA, 2000. Vol 3, Ch 4)."

3.2.1 Step 1 - Coordinate Agency Actions

When the risk assessment indicates the presence of contaminated fish and shellfish and a population of anglers likely to consume this fish and shellfish, members of LDEQ, LDWF and LDHH meet to discuss and weigh public health options.

Ultimately, an advisory is recommended when the LDHH determines that it is necessary to protect the public health. The SEET then develops a draft of the recommended fish / shellfish consumption advisory with the consultation and approval of the State Health Officer. The draft advisory along with the basis of the decision to issue the advisory (e.g., fish tissue data, meal limit calculations, relevant site-specific factors, etc.) is forwarded to the Secretaries (or designated representatives) of LDHH, LDEQ and LDWF for review. In order for the draft advisory to become public record, concurrence must first be obtained from the Secretaries and / or designated representatives of LDHH, LDEQ and LDWF. The LDAF is involved in the advisory process when the contaminant is a pesticide or agricultural in origin. Approval by the Commissioner of Agriculture and Forestry is required for the issuance of an advisory related to agricultural chemicals. Consultation with Centers for Disease Control (CDC) / ATSDR will be conducted as necessary. Figure 1 outlines these procedures.

3.2.2 Step 2 - Inform the Public

Once all involved agencies agree to the advisory, local officials are informed of the findings of the agencies and the pending issuance of a seafood consumption advisory. Following notification of the local officials, an announcement is made to the general public within three to five days. Some flexibility in the time elapsed between notification of local officials and the public is allowed during emergency events for more timely notification of the public. The public are notified of the advisory through a news release in the affected area and the SEET website. The basis of decision for the consumption advisory will be provided on the SEET and LDEQ websites and shall include sampling date; waterbody sampled; species sampled; contaminant assessed; tabulated sample results including average, minimum, and maximum contaminant concentrations; meal limit calculations; site-specific factors considered, and consumption advisory and precautionary postings where relevant. Following the issuance of the press release, the advisory is provided to the Louisiana State Library for distribution to all state repositories. Signs are posted at area public boat launches warning potential anglers about eating fish from the waterbody. Advisory information is also placed in the LDWF fishing regulations. Public meetings in local communities may be conducted to explain to local leaders and residents the fish / shellfish consumption advisory and the data on which it is based.

3.2.3 Step 3 - Advisory Re-Evaluation

When fish and shellfish data become available from a site with a consumption advisory, the site is re-characterized based on the newly calculated annual average chemical-specific fish-tissue concentrations. These revised annual average tissue concentrations are reviewed by LDHH, LDEQ, LDWF and LDAF and updates to advisories are recommended and discussed by all parties. Once the data review and risk analyses are completed, a plan of action is designed to update the advisory and inform the public of any changes in the existing advisory. The updating of the advisories may be categorized into two groups: 1) advisories which must be changed to reflect the current conditions and 2) advisories that remain unchanged because of little or no change in the analyses' results.

Trends in the fish-tissue contaminant data will be evaluated based on the mobility, bioaccumulation, and transport of the chemical(s) of concern (COCs). These trends are analyzed to prevent the variability of the data from adversely impacting risk assessment decisions. However, only one sampling event of adequate size and unacceptable average chemical concentration is necessary for issuance or continuance of an advisory.

In order to lift an advisory, average COC concentrations in fish / shellfish tissue samples must be acceptable (*i.e.*, below current TSL), for at least three consecutive sampling events over a minimum period of two years. Ongoing evaluation will occur to determine the need for changes in the fish / shellfish consumption advice given in the advisories.

If an advisory must remain in effect because health guidelines are exceeded in the trend analysis of the most recent data analyses, the local government is informed. A news release in the community lets the public know that the advisory has been reviewed and contamination is still present. The effectiveness of this public communication process regarding fish and shellfish advisories is evaluated by LDHH.

3.2.4 Step 4 – Advisory Rescinsion

To rescind an advisory, a rescinding letter is written by the State Health Officer and approved by the Secretaries and Assistant Secretaries of the LDHH, LDEQ and LDWF (and / or LDAF, if necessary). State officials, state agencies and local elected officials (e.g. mayors, parish councils, and / or police juries) in the area where the advisory is in effect are notified by LDHH. After local and state government is informed of the decision to lift advisory, a news release is issued in the community and major newspapers.

4.0 INSTRUCTIONS TO THE PUBLIC FOR USING ADVISORIES

The public is strongly encouraged to follow the instructions given in each health advisory. It is important to keep in mind that each advisory is issued for a particular area. Likewise, the health advice is also specific to the types and concentrations of chemicals identified at each site. Consequently, certain areas may have fish and shellfish consumption limits on specific species while another area may have a "no consumption" advisory on all fish and shellfish. The public should be aware that the health advisory is practical, protective advice reflecting all the best available data.

4.1 Sensitive Subpopulations

It is also important to understand that different groups within the general populations are more sensitive and may be considered by LDHH to tolerate different levels of contamination. Pregnant and breastfeeding women and young children require the most cautious and conservative approaches to health and risk analyses because developing fetuses and young children are especially sensitive. Also, anglers who may consume large quantities of fish and shellfish may be at greater risk for exposure to chemically contaminated fish and shellfish.

4.2 Food Preparation and Cooking

Most contaminants are lipophilic (*i.e.*, the chemicals tend to concentrate in the fat) so methods of preparation and cooking can also protect the public from contaminants in fish and shellfish. Trimming the fat and skin will reduce the amount of contaminants in the fish and shellfish. Cooking methods to minimize fat include baking, broiling, and grilling because the fat drains away from the fish and shellfish. The public is encouraged to discard the juices which contain the fat (and most of the toxins) to further reduce exposure. Some contamination, like mercury and other heavy metals, however, are pervasive in the edible fish tissue and remain in the fish and shellfish even after cooking.

5.0 NOTIFICATION OF STATE AGENCIES

5.1 Where to Report Suspected Seafood Contamination

The public should report suspected fish and shellfish contamination in store-bought or commercially-caught fish and shellfish to LDHH's Division of Sanitarian Services- Fish and Shellfish Unit (225-342-7550) or via the LDHH's Environmental Health Services Hotline (toll free at 1-800-256-2775). Complaints about recreationally-caught fish and shellfish that are suspected of being chemically contaminated are handled by LDHH's Section of Environmental Epidemiology and Toxicology (SEET) (888-293-7020). Office hours are 8:00 am to 4:30 pm Monday through Friday. There is also a statewide toll-free number to LDHH for the Office of Public Health where suspected chemical contamination of aquatic wildlife may be reported (1-800-256-4609).

Oyster harvesting is a major industry in Louisiana, and is strictly regulated by the LDHH's Molluscan Shellfish Program. Questions regarding oysters should be directed to 225-342-7617 or the statewide toll-free number 1-800-256-2775. This program monitors bacterial levels in oyster growing areas to determine which area are suitable for harvesting. There is a risk associated with consuming raw fish and shellfish as is the case with other raw protein products. A statewide health advisory warns that if a person suffers from chronic illness of the liver, stomach, or blood, or has other immune disorders, fish and shellfish should be eaten fully cooked. This advisory is required to be prominently posted at all establishments selling raw fish and shellfish for human consumption. It is based on the presence of non-pollutant, naturally-occurring bacteria in uncooked fish and shellfish, as well as the possibility of the presence of pollutant bacteria.

Advisories that involve bacterial or other infectious diseases are handled by LDHH's Division of Sanitarian Services in consultation with the Infectious Epidemiology Section of LDHH's Center for Community Health. Questions regarding bacterial levels in specific water bodies can be answered by contacting Sanitarian Services at 225-342-7550 or toll-free at 800-256-2775. Questions regarding diseases caused by bacteria may be answered by LDHH's Infectious Epidemiology Section at 800-256-2748. All of these offices can also be reached through the Office of Public Health's statewide toll free number 1-800-256-4609.

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TABLE

Table 1. Louisiana's Consumption Advisory Program's Current Default Assumptions^A (August 2008)

Table 1. Louisiana's Consumption Advisory Program's Current Default Assumptions (August 2008)							
Item	Issue	Definition	Alternate Assumptions (SEET, 2007)	LA Assumptions	Source Reference		
1	Fat Composition	Residual fat in seafood (ex. Crab) after cooking.	(1) Continuous range from 0 to 100%.	LA suggests removing fat before eating.	EPA, 1997. EPA, 2003. EPA, 2000.		
2	Consumption Rate	Amount of fish consumed on a daily basis.	(1) Continuous range from 20- 165 g/day	30 g/day for adults (or one 8 oz. (1/2 pound) meal/week or four 8 oz. meals/month). 15 g/day for children (or one 4 oz. (1/4 pound) meal/week or four 4 oz meals/month)	EPA, 1995. Ratard, 1993.		
3	Consumption Fraction	Fraction of individual seafood consumption from area.	(1) Continuous range from 0 to 100%	Irrelevant as advisories recommend site- specific meal limits (not total seafood limits); ³ Ratard, 1993.			
4	Exposure Duration	= (Exp Frequency (365 days) * Exp Duration (X))	(1) 30 yrs (2) 70 yrs	X= 30 yrs	EPA, 2000.		
5	Absorption Rate	Percentage of contaminant absorbed in the GI tract after seafood consumption.	(1) 100% default value	1 (100%).	EPA, 2000.		
6	Food Preparation and Cooking Reduction Factors	Percent reduction of a chemical due to meal preparation and / or cooking.	(1) 30% (2) 50% (3) 0% default value	0%	EPA, 2000.		
7	Acceptable Risk	Risk of developing disease for all exposed individuals.	(1) 1.00 x 10 ⁻⁴ (2) 1.00 x 10 ⁻⁵ (3) 1.00 x 10 ⁻⁶	1.00 x 10 ⁻⁴	EPA, 2000.		
8	Acceptable Hazard Quotient	Measure of potential for disease in exposed individuals	(1) 1.0	1.0	EPA, 2000.		
9	Non-Detect Treatment	Way of representing values for samples for which contaminants were not detected (below the detection limit).	(1) Zero (2) 1/2RL (half reporting limit)	Zero unless >1/2 samples from a waterbody are above RL then apply 1/2RL to non-detects	EPA, 2003. EPA, 2000. EPA, 1992.		
10	Fish Tissue Chemical Concentration Averaging Value	Numeric basis for fish advisory.	(1) Arithmetic Mean(2) Median(3) Geometric Mean	Arithmetic Mean	EPA, 2000.		
11	Species-specific Advisories	How fish are grouped as the basis for the advisory.	(1) Species-specific(2) Category (fin- or shell-fish)(3) All Seafood	Base advisories on species.	LDEQ, LDHH, LDWF consensus.		
12	Acceptable Meal Limit	The acceptable number of meals consumed on a monthly basis	(1) Range from 0.5 to 16 meals per month	4	EPA, 2000		

Notes: A. U.S. EPA-suggested body weights are applied. For adults these values are 70 and 35 kg kilograms for adults and children, respectively. **B.** U.S. EPA doesn't have specific advice (²EPA, 2003). A USDA study estimated crab fat to be 0.8% (raw) (¹EPA, 1997). EPA policy for crabs is: "*Edible tissue includes leg and claw meat, back shell meat and body cavity meat. Internal organs (hepatopancreas) are removed*" (⁴EPA, 2000).



Preliminary Data Collection Data Management Data Evaluation 1. Data QA/QC If data quality or 2. Comparison of tissue concentrations with TSL quantity 3. Identification of COC, species, and areas of potential concern inadequate If tissue concentration > TSL If tissue concentration \leq TSL No additional monitoring **Fish Consumption Advisory Process** until next screening sampling event **Comprehensive Data Collection Data Evaluation** 1. Data QA/QC 2. Calculation of tissue concentrations **Exposure Assessment Health Consultation** (as needed) (CDC/ATSDR) Calculation of allowable monthly meal limit **Environmental Investigation** If the allowable monthly If the allowable $meal\ limit \geq 4$ monthly meal limit <4 A consumption Risk No advisory is advisory is issued Communication needed at this time (All Agencies) (DHH)

Figure 1. Flowchart for Evaluation of Seafood Tissue Data